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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,256	09/13/2005	Angus Moodycliffe	112843-066	3290

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,256	MOODYCLIFFE ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005 & 29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This Office action completely supercedes any previous Office actions mailed to the applicant. Accordingly, the restriction requirement mailed to the applicant on September 1, 2006 is hereby vacated. Of note on the record, applicant's preliminary amendment filed on February 22, 2005 recites that "Claims 1-29 have been amended, newly submitted Claims 30-32 have been added" in lines 1-2 of the Remarks. See page 85. Accordingly, claims 1-32 are pending and subject to restriction/election requirement. Applicant is required to elect accordingly as indicated below.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3 and 6-8, drawn to a substance/composition capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a polynucleotide antisense to CD_{1d} mRNA.

Group II, claim(s) 1-3 and 6-8, drawn to a substance/composition capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a polynucleotide antisense to the glucosylceramide synthase mRNA.

Group III, claim(s) 1-3 and 6-8, drawn to a substance/composition capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a polynucleotide sense to the glucosylceramide synthase mRNA.

Group IV, claim(s) 1-3 and 6-8, drawn to a substance capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a polypeptide that is not an antibody.

Group V, claim(s) 1-3 and 6-8, drawn to a substance capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a lipid.

Group VI, claim(s) 1, 4, and 6-8, drawn to a substance capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a ligand of a receptor belonging to the TNF super family.

Group VII, claim(s) 1, 6-8, and 30, drawn to a substance capable of blocking or modifying endogenous CD_{1d} function, wherein the substance is a ligand of a receptor belonging to CD95/APO-1/Fas.

Group VIII, claim(s) 5, 9-15, 29, and 31-32, drawn to methods for preparing a carrier for the prevention of the detrimental effects of hair loss and for prevention of damage in epithelial tissues comprising the steps of using a substance capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide antisense to CD_{1d} mRNA.

Group IX, claim(s) 5, 9-15, 29, and 31-32, drawn to methods for preparing a carrier for the prevention of the detrimental effects of hair loss and for prevention of damage in epithelial tissues comprising the steps of using a substance capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide antisense to the glucosylceramide synthase mRNA.

Group X, claim(s) 5, 9-15, 29, and 31-32, drawn to methods for preparing a carrier for the prevention of the detrimental effects of hair loss and for prevention of damage in epithelial tissues comprising the steps of using a substance capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide sense to the glucosylceramide synthase mRNA.

Group XI, claim(s) 5, 9-15, 29, and 31-32, drawn to methods for preparing a carrier for the prevention of the detrimental effects of hair loss and for prevention of damage in epithelial tissues comprising the steps of using a substance capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide that is not an antibody.

Group XII, claim(s) 5, 9-15, 29, and 31-32, drawn to methods for preparing a carrier for the prevention of the detrimental effects of hair loss and for prevention of damage in epithelial tissues comprising the steps of using a substance capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide that is not an antibody.

Group XIII, claim(s) 5, 9-15, 29, and 31-32, drawn to methods for preparing a carrier for the prevention of the detrimental effects of hair loss and for prevention of damage in epithelial tissues comprising the steps of using a substance capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a lipid.

Group XIV, claim(s) 16-24, drawn to a method for identifying CD_{1d} blocking or modifying substances.

If group XIV is elected, applicants are further required to elect a single type of screening method as recited in claim 16 (c), a single pro-inflammatory cytokine from IL-1, TNF-α, PGE-2, IL-6, IFN-γ, and IL-8 of claim 19, AND a single type of immuno-modulatory cytokine from PAF, IL-10, IL-4, and TGF-β of claim 20, AND a single type of marker of aging from elastases, collagenases, metalloproteinases, gelatinases, stromelysins, and telomerases as recited in claim 24. Note these secondary requirements are not species election.

Group XV, claim(s) 25-26, drawn to a method for decreasing multi-drug resistance of cancers comprising the steps of administering to an individual taking a cancer drug a composition capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide antisense to CD_{1d} mRNA.

Group XVI, claim(s) 25-26, drawn to a method for decreasing multi-drug resistance of cancers comprising the steps of administering to an individual taking a cancer drug a composition capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide antisense to the glucosylceramide synthase mRNA.

Group XVII, claim(s) 25-26, drawn to a method for decreasing multi-drug resistance of cancers comprising the steps of administering to an individual taking a cancer drug a composition capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide sense to the glucosylceramide synthase mRNA.

Group XVIII, claim(s) 25-26, drawn to a method for decreasing multi-drug resistance of cancers comprising the steps of administering to an individual taking a cancer drug a composition capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide that is not an antibody.

Group XIX, claim(s) 25-26, drawn to a method for decreasing multi-drug resistance of cancers comprising the steps of administering to an individual taking a cancer drug a composition capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a polynucleotide that is not an antibody.

Group XX, claim(s) 25-26, drawn to a method for decreasing multi-drug resistance of cancers comprising the steps of administering to an individual taking a cancer drug a composition capable of blocking or modifying endogenous CD_{1d} function for prevention of hair loss, wherein the substance is a lipid.

Group XXI, claim(s) 27, drawn to a method of screening comprising the steps of using cells expressing and/or over-expressing CD_{1d} in an assay for screening for substances modifying and or blocking CD_{1d} function.

Group XXII, claim(s) 28, drawn to a method of determining activity of substances comprising the steps of using $CD_{1d}^{-/-}$ animals as a test model.

The inventions listed as Groups I-XXII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of group I is found to have no special technical feature that define a contribution over the prior art of Raz et al. (WO 00/62787). The special technical feature of invention of group I is a substance that modulates endogenous CD1d function. The reference of Raz et al., teaches an immunostimulatory oligonucleotide that modulates the host immune response to an antigen by potentiating the capacity of affected bone-marrow derived cells to take up present antisense through upregulation of CD1d expression (page 6). Therefore, applicants' invention of the substance capable of modulating CD1d function does not contribute a special technical feature when viewed over the prior art. Accordingly, the claimed inventions do not have a single inventive concept and so lack unity of invention, thus restriction for examination purposes as indicated is proper.

According to the guidelines in Section (f)(i)(a) of Annex B of the PCT Administrative Instructions, the special technical feature as defined by PCT Rule 13.2 shall be considered to be met when all the alternatives of a Markush-group are of similar nature when:

(A) all alternatives have a common property or activity and

(B)(1) a common structure is present, i.e, a significant structure is shared by all of the alternatives or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to an art recognized class of compounds in the art to which the invention pertains.

The instant screening methods are considered to be each separate invention for the following reasons:

As described above, the screening methods do not meet the criteria of (A), common property or activity and (B)(1) common structure. Although all methods disclosed as screening assays are directed to screening for characteristics of cell biology, each screening method comprises different method steps and ingredients that are not shared by another and each method assays for and measures different aspects of cell biology. Therefore, each member of the class cannot be substituted one for the other, with the expectation that the same intended result would be achieved. Accordingly, unity of invention among different types of assays is lacking, and each assay method is considered to constitute a special technical feature.

The members of Markush groups below are considered to be each separate invention for the following reasons:

The Markush group of cytokines or markers set forth in claims 19-20 and 24 are distinct proteins that do not have a common amino acid sequence or nucleic acid sequence, having different structural and functional properties that are not shared by another protein. Accordingly,

unity of invention among different types of proteins is considered to constitute a special technical feature.

Conclusion

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

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